



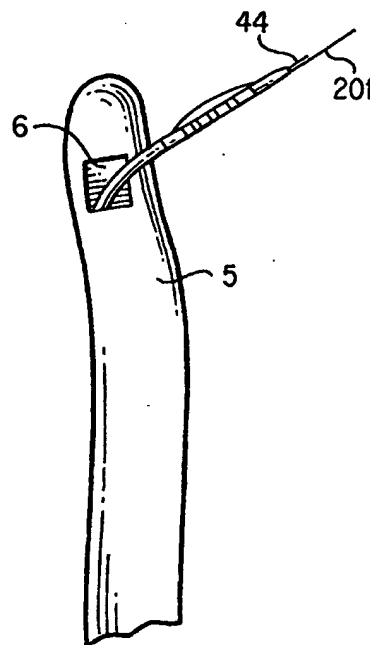
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(54) Title: DEVICE AND METHOD FOR FACILITATING ACCESS TO A DUCT WITHIN THE HUMAN BODY

(57) Abstract

An improved device and method for facilitating access to a duct within the human body. The device includes a multi-lumen catheter having a sphincterotome cutting wire disposed through a first lumen and attached at its proximal end to a sphincterotome deployer, and a needle knife cutting wire disposed through a second lumen and attached at its proximal end to a needle knife deployer. By using this device, a physician can perform both standard endoscopic sphincterotome sphincterotomy and needle knife sphincterotomy without having to exchange instruments through the endoscope. In this manner, the physician can more effectively and efficiently gain access to a duct within the human body. A method for performing combined sphincterotome and needle knife sphincterotomy is also provided wherein it is no longer necessary to remove one of the two instruments from the endoscope before the other instrument can be used.



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Device and Method for Facilitating Access to a
Duct Within the Human Body

Field of the Invention

The present invention relates generally to the field of surgery, and more particularly to an improved device and method for facilitating access to a duct
5 within the human body.

Background of the Invention

A person may experience a gallbladder attack when gallstones form in the gallbladder and become too large
10 to pass through the cystic duct and the common bile duct and into the duodenum. Such an attack can cause intense pain and may require that the person's gallbladder be surgically removed. Where the site of the blockage is the sphincter of Oddi, however, a physician may use a
15 less traumatic procedure to cut the sphincter sufficiently to permit even large size gallstones to pass into the duodenum. This procedure is referred to as "ERS," or "endoscopic retrograde sphincterotomy."

When performing ERS, a physician introduces a side-
20 viewing endoscope through the patient's esophagus, into the stomach, through the pyloric sphincter, and into the duodenum. Next, the physician positions the endoscope near the papilla of Vater and then threads a catheter through the endoscope, through the sphincter of Oddi,
25 and into the bile duct. At this point, the physician may inject a radio-opaque contrast fluid through the catheter and into the patient. By using contrast fluid, the physician may view any gallstones fluoroscopically and evaluate their size. If a stone is found to be too
30 large to pass through the sphincter of Oddi even if the

sphincter of Oddi is enlarged, the ERS procedure is contraindicated and the patient should be considered an abdominal surgery candidate. However, if the size of the gallstones are sufficiently small that they could
5 pass through the sphincter of Oddi if it was enlarged, then the physician will attempt to cut the sphincter of Oddi and thereby enlarge it.

Alternately, a physician may determine that the sphincter of Oddi needs to be enlarged even before the
10 physician can properly cannulate and visualize the bile duct. Also, a physician may determine that there is no need to visualize the obstruction with contrast fluid and may instead just decide to enlarge the sphincter of Oddi so that the obstruction may pass through the
15 sphincter of Oddi and into the duodenum.

Two procedures for electrosurgically cutting the sphincter of Oddi and thereby facilitating access to the biliary tree are well known in the art. The first is to use an electrosurgical sphincterotome to cut the papilla
20 of Vater of the sphincter of Oddi partially open. The second is to use an electrosurgical needle knife to perform the same function.

Electrosurgical sphincterotomes are well known. An electrosurgical sphincterotome has a cutting wire that
25 extends the length of the catheter and forms a cutter outside of the catheter. The proximal end of the cutting wire is in electrical communication with an external power source. To cut the desired tissue, the physician energizes the cutting wire and manipulates the
30 sphincterotome cutter to cut the targeted tissue. There are at least two ways by which the cutter cuts the targeted tissue. The first method is by electrical arcing; the patient is grounded and electrical energy from the cutter is transferred to the targeted tissue
35 when the cutter approaches the tissue. The second method is by thermal radiation; the temperature of the cutter is increased by electrical resistance, and

thermal energy from the cutter is transferred to the targeted tissue when the cutter approaches the tissue.

Electrosurgical needle knives are similarly well known. An electrosurgical needle knife has a cutting
5 wire that extends the length of the catheter and forms a cutting wire tip outside of the catheter. The proximal end of the cutting wire is in electrical communication with an external power source. To cut the desired
10 tissue, the physician energizes the cutting wire and manipulates the cutting wire tip to cut the targeted tissue. Like the cutter described above, the cutting wire tip also cuts the targeted tissue through either electrical arcing or thermal radiation.

Electrical energy is controlled to provide cautery
15 as well as cutting action. This energy is applied in the form of R/F (radio frequency) energy, the frequency and amplitude of which are factors in both cutting and cautery procedures.

United States Patent No. 5,024,617 to Karpziel,
20 incorporated herein by reference, generally discloses a method of using a sphincterotome for cutting the sphincter of Oddi. Several types of sphincterotomes are also disclosed in that reference.

United States Patent Nos. 5,536,248 and 5,599,300,
25 both to Weaver et al., disclose a method of using a needle knife for cutting the sphincter of Oddi. Both of these patents are incorporated herein by reference.

It is also known that when using either a sphincterotome or a needle knife, it is preferable to
30 have the instrument disposed through a multi-lumen catheter. By dedicating one lumen of the catheter to hold the instrument, the physician is free to use the other lumen(s) for a guide wire or for injecting contrast fluid. The advantages of using a multi-lumen
35 catheter when facilitating access to the biliary tree are generally disclosed in United States Patent No. 5,547,469 to Rowland et al., and in United States Patent

No. 5,599,299 to Weaver et al., both of which are also incorporated herein by reference.

Currently, Boston Scientific Corporation markets a three lumen instrument called the "Ultratome XL." The first lumen of the "Ultratome XL" contains an electrosurgical sphincterotome, and the second and third lumens are used respectively for a guide wire and contrast fluid. The "Ultratome XL," however, does not include a needle knife.

10 The merits of performing a needle knife sphincterotomy as opposed to a standard endoscopic sphincterotomy sphincterotomy have been widely discussed in the medical art. In general, the needle knife procedure is seen as an alternative technique for
15 gaining access to the bile duct when the standard method of sphincterotomy sphincterotomy fails to provide the physician with access. When switching from sphincterotomy sphincterotomy to needle knife sphincterotomy, however, the physician must first remove
20 the sphincterotome from the patient and then insert a needle knife. Switching instruments, however, wastes valuable time during a procedure and will require the physician to expend additional time repositioning the new instrument at the desired location. Although a
25 physician who is using multiple-lumen instruments in conjunction with a guide wire (such as the "Ultratome XL") may be able to switch instruments without having to reposition the guide wire, there still is a delay while the sphincterotome is first removed and the needle knife
30 is inserted.

 In addition, should the physician wish to return to using the sphincterotome after performing a procedure with the needle knife, the physician would once again have to withdraw the needle knife entirely and then
35 reinsert, reposition, and readjust the sphincterotome.

 Although needle knife sphincterotomy is generally seen as an alternative approach to be used when standard

sphincterotome sphincterotomy is unsuccessful, some physicians prefer to use both instruments routinely when attempting to gain access to the bile duct. With the current state of the medical art, however, these
5 physicians must remove one instrument entirely before they are able to use the other. Therefore it would be desirable to provide an instrument that is a combination of a sphincterotome and a needle knife for use in performing a sphincterotomy.

10

Summary of the Invention

In light of the above, an improved device and method for facilitating access to a duct within the human body is provided. The device includes a multi-
15 lumen catheter having a sphincterotome cutting wire disposed through a first lumen and attached at its proximal end to a sphincterotome deployer, and a needle knife cutting wire disposed through a second lumen and attached at its proximal end to a needle knife deployer.
20 By using this device, a physician can perform both standard endoscopic sphincterotome sphincterotomy and needle knife sphincterotomy without having to exchange instruments through the endoscope. In this manner, the physician can more effectively and efficiently gain
25 access to a duct within the human body.

A method for performing combined sphincterotome and needle knife sphincterotomy is also provided wherein it is no longer necessary to remove one of the two instruments from the endoscope before the other
30 instrument can be used.

Brief Description of the Drawings

The invention will be more readily understood through the following detailed description, with
35 reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of the preferred embodiment of the present invention;

Fig. 2 is a partially cross-sectional view of the preferred embodiment of the present invention, showing the needle knife in its fully-deployed position;

Fig. 2A is a cross-sectional view of the three-lumen catheter used in the preferred embodiment of the present invention;

Fig. 2B is a cross-sectional view of a four-lumen catheter that may be used in the present invention;

Fig. 3 is an enlarged detailed view of the working end of the present invention as shown in Fig. 2;

Fig. 4 is a partially cross-sectional view of the preferred embodiment of the present invention, showing the needle knife in its fully-retracted position;

Fig. 5 is an enlarged detailed view of the working end of the present invention as shown in Fig. 4;

Fig. 6 is an enlarged detailed sectional view of the deployer end of the needle knife used in the preferred embodiment of the invention;

Fig. 7 is an enlarged detailed sectional view of the deployer end of the sphincterotome used in the preferred embodiment of the invention;

Fig. 8 illustrates an endoscope near the point of introduction into the common bile duct;

Fig. 9 is an enlarged detailed view of a needle knife/sphincterotome of the present invention extending through the accessory channel of an endoscope with the cutting wire of the sphincterotome in a straight position, and the needle knife in a fully-extended position; and

Fig. 10 is an enlarged view of a needle knife/sphincterotome of the present invention extending through the accessory channel of an endoscope at the point of introduction into the common bile duct with the cutting wire of the sphincterotome pulled tight, and the needle knife in a fully-retracted position.

Detailed Description

As seen in Fig. 1, the present invention comprises a needle knife 1, a sphincterotome 4, and a multi-lumen catheter 7. The needle knife 1 is attached to the catheter 7 at an injection port 10 by a luer lock 13, while the sphincterotome 4 is attached to the catheter 7 by heat shrink material 16. In the preferred embodiment of the invention, both the needle knife 1 and the sphincterotome 4 are fixedly attached to the catheter 7. Alternately, the needle knife 1 may be removably attached to the catheter 7 so that fluid (such as radio-opaque contrast fluid) or another instrument may be disposed through the injection port 10 when the needle knife 1 is not attached to the catheter 7.

The catheter 7 has a substantially cylindrical shape and a substantially uniform diameter. The catheter 7 is specifically designed and sized to be introduced into a duct or body passage of a patient through the accessory channel 6 of a standard endoscope 5 (as seen in Fig. 9). The catheter 7 used in the preferred embodiment of the invention is preferably made of Teflon® to facilitate its easy insertion into the body, and has a length sufficient to extend the length of a standard accessory channel 6 and to reach sufficiently into the duct or passage. The preferred working length of the catheter 7 (i.e., the length of the catheter 7 excluding the proximal portion that does not enter the endoscope 5) for use on an adult patient is approximately between 190 and 205 centimeters. As seen in Fig. 2, the catheter 7 narrows near its distal tip 22 and forms a working end 23. The working end 23 is that portion of the catheter 7 that is designed to exit the endoscope 5 and enter the duct or body passage of the patient. Preferably the length of the working end 23 for use on an adult patient is approximately between six and nine centimeters.

In the preferred embodiment of the invention, the catheter 7 has three lumens 7a, 7b, and 7c (shown in

Fig. 2A) extending lengthwise therethrough. The first lumen 7a is for receiving a cutting wire 28 of the sphincterotome 4, the second lumen 7b is for receiving a cutting wire 41 of the needle knife 1, and the third lumen 7c is for receiving a guide wire 201. Additional lumen (such as fourth lumen 7d shown in Fig. 2B) may also be provided for carrying contrast fluid, saline solution, additional instruments, or other items or fluids that a physician may wish to introduce into the patient during a given procedure.

In the preferred embodiment of the invention, both the second and third lumens of the catheter 7 exit the catheter 7 at its distal tip 22 in a generally distal direction. As seen in Fig. 3, however, the first lumen does not exit the catheter 7 at its distal tip 22, but rather near the distal tip 22 through a cutting wire port 25. This arrangement is well known in the art and allows the sphincterotome cutting wire 28 to exit the catheter 7 through the cutting wire port 25 and thereby become a cutter 31. The cutter 31 is bowed between a first location 37 and a second location 38 on the outside of the catheter 7. The cutter 31 re-enters the catheter 7 and, preferably, the first lumen, through an anchor port 34 and is anchored within the catheter 7 as is well known. Although the cutter 31 is shown bowed in Fig. 3 (and Fig. 5) for purposes of illustration, it is understood that in practice, the cutter 31 straightens out (and the catheter 7 flexes) when the cutter 31 is used to incise tissue (as shown in Fig. 10).

Detailed depictions of the proximal and distal ends of the present invention are provided in Figs. 2 and 4, wherein a substantial portion of the length of the catheter 7 has been redacted to facilitate the illustration of the present invention.

With reference again to Fig. 2, the proximal end of the third lumen terminates at a guide wire port 19. It is through guide wire port 19 and through the third

lumen that the guide wire 201 may be inserted and threaded prior to introduction of the catheter 7 into the endoscope 5. The use of one or more guide wires for positioning a catheter within a patient is well known in the art. The guide wire 201 is preferably fed into and out of the third lumen of the catheter 7 by hand, although using a guide wire feed device (not shown), such the guide wire feed device disclosed in United States Patent No. 5,599,300 by Weaver et al., is also well known. The guide wire feed device may be attached to the guide wire port 19. Preferably the guide wire 201 has a diameter of approximately .035 inches and is coated with a hydrophilic coating to facilitates its easy insertion and removal through the catheter 7.

As seen in Fig. 2, the needle knife 1 is fixedly attached to catheter 7 at the injection port 10 by the luer lock 13. Alternately, the needle knife 1 may be attached to catheter 7 with heat shrink material (not shown). Similarly, while it is preferable to attach the sphincterotome 4 to the catheter 7 with heat shrink material 16 (not shown in Fig. 2), the sphincterotome 4 may be fixedly or releasably attached to the catheter 7 with a luer lock or other fastener. The needle knife cutting wire 41 extends longitudinally from the needle knife 1, through the second lumen, and, in its fully-deployed position, exits the distal tip 22 of the catheter 7 to form a needle knife cutting tip 44. In its fully-deployed position, it is preferable that the needle knife cutting tip 44 extend approximately ten millimeters beyond the distal tip 22 of the catheter 7 when the catheter 7 is in a straight configuration.

Fig. 6 depicts the internal structure of the deployer end of the needle knife 1 used in the preferred embodiment of the invention. The two main parts of needle knife 1 are the needle knife cutting wire 41 and the needle knife cutting wire deployer 2. The needle knife cutting wire deployer 2 used in the preferred

embodiment of the invention is principally comprised of a body 61 and a piston 62 that slidably engages the body 61. A luer lock 13 is provided at the distal end of the body 61 for attaching the body 61 to the injection port 10. A thumb ring 63 is attached to the proximal end of the piston 62, and a finger grip 73 covers the proximal end of the body 61. By grasping the thumb ring 63 and finger grip 73, the user of the needle knife 1 is able to manipulate the position of the piston 62 relative to the body 61. As will be discussed below, the piston 62 is free to move longitudinally within the body 61 between a fully-retracted position and a fully-deployed position.

The body 61 defines a slot 75 through which a first socket set screw 71 extends from the piston 62. A banana plug assembly 77 is attached to the first socket set screw 71, and therefore the banana plug assembly 77 is attached to the piston 62. The banana plug assembly 77 is comprised of a banana plug 69 and a banana plug sheath 65, and the banana plug 69 is used for making an electrical connection to a power source (not shown) to provide a cutting/coagulating current to the needle knife cutting wire 41, as is well known in the art.

The proximal end of the needle knife cutting wire 41 is disposed longitudinally through the body 61 and the piston 62, and is fixedly attached to the piston 62 by the first socket set screw 71 and a second socket set screw 72, both preferably made of stainless steel, and a conductive disc 76, preferably made of aluminum. As discussed previously, the majority of the needle knife cutting wire 41 is disposed through the second lumen of the catheter 7 and extends longitudinally to the distal tip 22 of the catheter 7. When the needle knife 1 is in its fully-deployed position, the needle knife cutting wire 41 exits the distal tip 22 of the catheter 7 and forms a needle knife cutting tip 44 that extends approximately ten millimeters beyond the distal tip 22

of the catheter 7 when the catheter 7 is in a straight configuration. When the needle knife 1 is in its fully-retracted position, the needle knife cutting tip 44 remains entirely within the second lumen of the catheter 7 and does not exit the distal tip 22 of the catheter 7.

As the first socket set screw 71 is used to connect the banana plug assembly 77 to the piston 62, and the needle knife cutting wire 41 is attached to the first socket set screw 71, the needle knife cutting wire 41 is therefore fixedly connected to the banana plug assembly 77. Furthermore, as the first socket set screw 71 and the conductive disc 76 are preferably made of a conductive material, such as stainless steel and aluminum respectively, the needle knife cutting wire 41 is also electrically connected to the banana plug 69 of the banana plug assembly 77.

As discussed above, the user of the needle knife 1 is free to move the piston 62 longitudinally within the body 61 by applying the necessary force to the thumb ring 63 relative to the finger grip 73. By sliding the thumb ring 63 toward the finger grip 73, the user deploys the needle knife cutting wire 41 through the distal tip 22 of the catheter 7. By sliding the thumb ring 63 away from the finger grip 73, the user retracts the needle knife cutting wire 41 and the needle knife cutting tip 44 into the second lumen within the distal tip 22 of the catheter 7. An O-ring 80 is provided to help ensure that any movement of the piston 62 with respect to the body 61 is smooth and continuous when a given force is applied to the thumb ring 63.

The range of motion of the piston 62 relative to the body 61 is between a fully-deployed position and a fully-retracted position. As the piston 62 is moved within the body 61 between the fully-deployed position and the fully-retracted position, the first socket set screw 71, which extends through the slot 75 of the body 61, likewise moves relative to the body 61. The slot

75, however, extends from a first position 78 (proximal on the body 61) to a second position 79 (distal on the body 61). Therefore, when the first socket set screw 71 or a component of the banana plug assembly 77 comes in
5 contact with the body 61 at the first position 78, the banana plug assembly 77 is restricted from moving further in a proximal direction. This point, therefore, defines the fully-retracted position of the needle knife 1. Likewise, when the first socket set screw 71 or a
10 component of the banana plug assembly 77 comes in contact with the body 61 at the second position 79, the banana plug assembly 77 is restricted from moving further in the distal direction. This point, therefore, defines the fully-deployed position of the needle knife
15 1.

In the preferred embodiment of the invention, the element that comes in contact with the body 61 at either the first position 78 or second position 79 is the first socket set screw 71. It is recognized, however, that a
20 component of the banana plug assembly 77, such as the banana plug sheath 65, may be relied on to restrict the movement of the piston 62 relative to the body 61, or other means may be provided to limit the motion of the piston 62 relative to the body 61.

25 In the preferred embodiment of the invention, the cutting wire 41 of the needle knife 1 has a diameter of approximately .01 inches and is made from stainless steel.

30 With reference to Fig. 7, the internal structure of the deployer end of the sphincterotome 4 used in the preferred embodiment of the invention will now be described.

The two main parts of the sphincterotome 4 are the sphincterotome cutting wire 28 and the sphincterotome
35 cutting wire deployer 3. The sphincterotome cutting wire deployer 3 used in the preferred embodiment of the invention is principally comprised of a fixed member 90

and a sliding body 87, which surrounds and slidably engages the fixed member 90. A thumb ring 93 is attached to the proximal end of the fixed member 90, and fingers grips 96 are integrally connected to the sliding body 87. By grasping the thumb ring 93 and finger grips 96, the user of the sphincterotome 4 is able to manipulate the position of the sliding body 87 relative to the fixed member 90. As will be discussed below, the sliding body 87 is free to move longitudinally over the fixed member 90 between a fully-retracted position and a fully-deployed position.

A banana plug assembly 99 is attached to the sliding body 87 by a first socket set screw 225 and a fastener 215. The first socket set screw 225 passes through the fixed member 90 through a slot (not shown). The banana plug assembly 99 is comprised of a banana plug 220 and a banana plug sheath 230. The banana plug 220 is used for making an electrical connection to a power source (not shown) to provide a cutting/coagulating current to the sphincterotome cutting wire 28, as is well known in the art.

The sphincterotome cutting wire 28 is disposed longitudinally through the sliding body 87 and the fixed member 90. The sphincterotome cutting wire 28 also passes through side holes (not shown) of an insert 70, which snugly engages the sliding body 87 and is open at one end 300. A second socket set screw 235 is contained within the insert 70, which is threaded to receive and fixedly attach screws 225 and 235 to the insert 70. Accordingly, a portion of the sphincterotome cutting wire 28 is sandwiched between the second socket set screw 235 on one side, and a conductive disc 240 and the first socket set screw 225 on the other side. The first socket set screw 235 extends through the opening at the end 300 of the insert 70 and is attached to the banana plug assembly 99 by the fastener 215. As the insert 70 is snugly engaged with the sliding body 87 and the

socket set screws 225 and 235 are fixedly attached to the insert 70, both socket set screws 225 and 235 and the conductive disc 240 are likewise fixedly attached to the sliding body 87. The socket set screws 225 and 235
5 are preferably made of stainless steel, and the conductive disc 240 is preferably made of aluminum.

As the sphincterotome cutting wire 28 is fixedly attached to the second socket set screw 235 and the conductive disc 240, the sphincterotome cutting wire 28
10 is also fixedly attached to the sliding body 87 and to the banana plug assembly 99. Furthermore, as the first socket set screw 225 and the conductive disc 240 are preferably made of conductive materials, such as stainless steel and aluminum respectively, the
15 sphincterotome cutting wire 28 is also electrically connected to the banana plug 220 of the banana plug assembly 99.

As discussed previously, the majority of the sphincterotome cutting wire 28 is disposed through the
20 first lumen of catheter 7 and extends longitudinally to the distal tip 22 of catheter 7. As seen in Fig. 3, the first lumen exits the catheter 7 near its distal tip 22 through a cutting wire port 25. This arrangement is well known in the art and allows the sphincterotome
25 cutting wire 28 to exit the catheter 7 through the cutting wire port 25 and thereby become the cutter 31. As discussed previously, the cutter 31 is "bowed" between a first location 37 and a second location 38 on the outside of catheter 7. The cutter 31 re-enters the
30 catheter 7 and, preferably, the first lumen, through the anchor port 34 and is anchored within the catheter 7 as is well known.

When the sphincterotome 4 is in its fully-deployed position, the distal tip 22 of the catheter 7 remains in
35 a generally longitudinal alignment. When the sphincterotome 4 is in its fully-retracted position, however, the cutter 31 will pull tight and deform the

distal tip 22 of the catheter 7 from its generally longitudinal alignment (as seen in Fig. 10). A physician may use the cutter 31 of the sphincterotome 4 in any position ranging from its fully-retracted position to its fully-deployed position.

As discussed above, and with reference to Fig. 7, the user of the sphincterotome 4 is free to move the sliding body 87 longitudinally over the fixed member 90 by applying the necessary force to the finger grips 96 relative to the thumb ring 93. By sliding the finger grips 96 away from the thumb ring 93, the user reduces the tension on the sphincterotome cutting wire 28, thereby allowing the distal tip 22 of the catheter 7 to return to a generally longitudinal alignment. By sliding the finger grips 96 toward the thumb ring 93, the user applies tension to the sphincterotome cutting wire 28 and the cutter 31 will pull tight and deform the distal tip 22 of the catheter 7 from its generally longitudinal alignment.

The range of motion of the sliding body 87 relative to the fixed member 90 is between a fully-deployed position and a fully-retracted position. As the sliding body 87 is moved over the fixed member 90 between the fully-deployed position and the fully-retracted position, the sliding body 87 comes in contact with the fixed member 90 at a first position 206 and is restricted from moving further in a proximal direction. This point, therefore, defines the fully-retracted position of the sphincterotome 4. Likewise, when the sliding body 87 comes in contact with the fixed member 90 at a second position 207, it is restricted from moving further in the distal direction. This point, therefore, defines the fully-deployed position of the sphincterotome 4.

In the preferred embodiment of the invention, the sphincterotome cutting wire 28 and the cutter 31 are all

formed from a single strand of stainless steel wire having a diameter of approximately .01 inches.

After using the needle knife/sphincterotome of the present invention to perform either a sphincterotome sphincterotomy, a needle knife sphincterotomy, or a combination of both forms of sphincterotomies, the physician can insert the catheter 7 into the common bile duct 108 with little effort. Once access to the biliary tree has been achieved, the physician can then cannulate and visualize the area by injecting contrast fluid through a fourth lumen of the catheter 7, through a lumen of the needle knife 1 (if the needle knife 1 is hollow and has a lumen), or through either the first, second, or third lumen if the physician removes the sphincterotome 4, the needle knife 1, or the guide wire 201 from the catheter 7. The physician may also perform additional surgical procedures, such as the introduction and removal of stents, or may use an additional instrument, such as a biopsy cutter, stone extractor, forcep, or the like, through a fourth lumen of the catheter 7 or through either the first, second, or third lumen if the physician removes the sphincterotome 4, the needle knife 1, or the guide wire 201 from the catheter 7. Alternately, the physician may forgo the use of a guide wire 201 altogether and use the third lumen (and possibly a fourth lumen) for either injecting contrast fluid or for an additional instrument.

Use of the device described above saves considerable time over the use of prior art devices. When using prior art devices, a physician who wished to switch between a sphincterotome and a needle knife (and possibly back again) when attempting to gain access to the biliary tree had to first withdraw one instrument through the catheter 7 before inserting and using a second instrument.

A method of using the preferred embodiment of the present invention will now be described with reference

to Figs. 8 - 10. As an initial matter, the patient is sedated or placed under general anesthesia.

As seen in Fig. 8, the physician introduces a side-viewing endoscope 5 through the patient's esophagus, into the stomach, through the pyloric sphincter, and into the duodenum 101. The physician then positions the endoscope 5 near the sphincter of Oddi 104 in the papilla of Vater 107. The endoscope 5 is positioned to allow the physician to view the sphincter of Oddi 104 as is known. Next, the physician may advance a guide wire (not shown) through the accessory channel 6 of the endoscope 5 and position the guide wire at the point near the sphincter of Oddi where the physician desires to place the catheter 7. The catheter 7 is then threaded over the guide wire through the third lumen of the catheter 7 and is positioned near the sphincter of Oddi 104.

With reference to Fig. 10, after the catheter 7 has been properly positioned, the physician advances the catheter 7 into engagement with the sphincter of Oddi 104 by inserting the distal tip 22 into the ampulla of Vater, which communicates with the common bile duct 108 and the pancreatic duct 109. At this point, the physician then selects to perform either a sphincterotome sphincterotomy, a needle knife sphincterotomy, or a combination of the two.

Fig. 10 shows a sphincterotome sphincterotomy being performed on a patient's sphincter of Oddi 104. When performing a sphincterotome sphincterotomy, the physician orients the cutter 31 of the sphincterotome 4 so that the cutter 31 and the catheter 7 are oriented radially with respect to the central ampulla of Vater. As is well known in the art, it is preferable that the cutter be oriented to the 12 o'clock position of the papillary orifice to avoid injury to the duodenal wall or pancreatic duct 109. The physician then energizes the sphincterotome cutting wire 28 and the cutter 31,

manipulates the position of the cutter 31 by using the elevator and/or positioning controls of the endoscope 5 and/or by using the sphincterotome cutting wire deployer 3, and cuts the sphincter of Oddi 104 radially outward of the center of the sphincter of Oddi 104. The physician controls the amount of "bow" in the cutter 31 by manipulating the sliding body 87 of the sphincterotome 4 relative to the fixed member 90 as explained previously.

When performing a needle knife sphincterotomy, the physician advances the thumb ring 63 of the needle knife 1 toward the body 61, thereby deploying the needle knife cutting tip 44 through the distal tip 22 of the catheter 7 to its proper length. The physician then energizes the needle knife cutting wire 41 through the banana plug 69, manipulates the position of the needle knife cutting tip 44 by using the elevator and/or positioning controls of the endoscope 5 and/or by using the needle knife cutting wire deployer 2, and incises the targeted tissue. After the desired incision in the sphincter of Oddi 104 has been made, the physician retracts the needle knife cutting tip 44 into the second lumen of the catheter 7 by withdrawing the thumb ring 63 away from the body 61 of the needle knife 1. At this point, the physician may elect to perform a sphincterotome sphincterotomy.

Regardless, the physician, after performing either a sphincterotome sphincterotomy, a needle knife sphincterotomy, or a combination of both forms of sphincterotomies, can now insert the catheter 7 into the common bile duct 108 with little effort. Once access to the biliary tree has been achieved, the physician can then cannulate and visualize the area by injecting contrast fluid through a fourth lumen or through either the first, second, or third lumen if the physician removes the sphincterotome 4, the needle knife 1, or the guide wire 201 from the catheter 7. The physician may

also perform additional surgical procedures, such as the introduction and removal of stents, or may use an additional instrument, such as a biopsy cutter, stone extractor, forcep, or the like, through a fourth lumen
5 or through either the first, second, or third lumen if the physician removes the sphincterotome 4, the needle knife 1, or the guide wire 201 from the catheter 7.

Alternately, the physician may remove the catheter 7 and thread a new catheter, capable of carrying
10 contrast fluid and/or one or more additional instruments, into the common bile duct 108 or any other duct or body passage. When threading a new catheter into a duct or body passage, the physician may remove the catheter 7 of the present invention over the guide
15 wire 201 and thread the new catheter over the still properly-positioned (or subsequently repositioned) guide wire 201 and into the desired location within the duct or body passage.

The method described above saves considerable time
20 over the use of prior art procedures. When following a prior art procedure, a physician who wished to switch between a sphincterotome and a needle knife (and possibly back again) when attempting to gain access to the biliary tree had to first withdraw one instrument
25 through the catheter 7 before inserting and using a second instrument.

Although the preferred embodiment of the invention has been described in connection with gaining access to the biliary tree, the present invention may be used
30 anywhere tissue cutting or desiccation is required. In addition, other objects and advantages of the present invention will become readily apparent to those skilled in this art from the above-recited detailed description, as only the preferred embodiment of the invention has
35 been shown and described. The description of the preferred embodiment is simply by way of illustration of the best mode contemplated for carrying out the

invention. As will be realized, the invention is capable of other and different embodiments, and its several details are capable of modification in various respects, all without departing from the invention.

- 5 Accordingly, the drawings and descriptions are to be regarded as illustrative in nature, and not as restrictive.

What is claimed is:

- 1 1. A device for facilitating access to a duct within
2 the human body, comprising:
 - 3 a. a catheter having a proximal end and a distal
4 end and defining a first lumen and a second
5 lumen therethrough, wherein said first lumen
6 extends longitudinally through said catheter
7 from a first port near said proximal end of
8 said catheter to a first opening near said
9 distal end of said catheter, and said second
10 lumen extends longitudinally through said
11 catheter from a second port near said proximal
12 end of said catheter to a second opening near
13 said distal end of said catheter;
 - 14 b. a first cutting/coagulating element disposed
15 through said first lumen; and
 - 16 c. a second cutting/coagulating element disposed
17 through said second lumen.

- 1 2. A device for facilitating access to a duct within
2 the human body, comprising:
 - 3 a. a catheter having a proximal end and a distal
4 end and defining a first lumen and a second
5 lumen therethrough, wherein said first lumen
6 extends longitudinally through said catheter
7 from a first port near said proximal end of
8 said catheter to a first opening near said
9 distal end of said catheter, and said second
10 lumen extends longitudinally through said
11 catheter from a second port near said proximal
12 end of said catheter to a second opening near
13 said distal end of said catheter;
 - 14 b. a first cutting/coagulating element disposed
15 through said first lumen and having a proximal
16 end attached to a first element deployer; and

17 c. a second cutting/coagulating element disposed
18 through said second lumen and having a
19 proximal end and a distal tip, said proximal
20 end of said second cutting/coagulating element
21 being attached to a second element deployer.

1 3. The device as recited in claim 2, wherein said
2 catheter defines a third lumen extending
3 longitudinally through said catheter from a third
4 port near said proximal end of said catheter to a
5 third opening near said distal tip of said
6 catheter.

1 4. The device as recited in claim 3, further
2 comprising:
3 a guide wire disposed through said third
4 lumen.

1 5. The device as recited in claim 4, further
2 comprising:
3 a guide wire feed device attached to said
4 third port of said catheter for moving said
5 guide wire through said third lumen.

1 6. The device as recited in claim 3, wherein said
2 catheter defines a fourth lumen extending
3 longitudinally through said catheter.

1 7. The device as recited in claim 4, wherein when said
2 guide wire is removed from said third lumen, fluid
3 or an instrument may be passed through said third
4 lumen.

1 8. The device as recited in claim 7, wherein said
2 catheter defines a fourth lumen extending
3 longitudinally through said catheter.

- 1 9. The device as recited in claim 2, wherein when said
2 second cutting/coagulating element is removed from
3 said second lumen, fluid or an instrument may be
4 passed through said second lumen.
- 1 10. The device as recited in claim 9, wherein said
2 catheter defines a third lumen extending
3 longitudinally through said catheter from a third
4 port near said proximal end of said catheter to a
5 third opening near said distal tip of said
6 catheter.
- 1 11. The device as recited in claim 10, further
2 comprising:
3 a guide wire disposed through said third
4 lumen.
- 1 12. The device as recited in claim 11, wherein when
2 said guide wire is removed from said third lumen,
3 fluid or an instrument may be passed through said
4 third lumen.
- 1 13. The device as recited in claim 12, wherein said
2 catheter defines a fourth lumen extending
3 longitudinally through said catheter for passing
4 fluid or an instrument therethrough.
- 1 14. The device as recited in claim 2, wherein when said
2 second cutting/coagulating element is removed from
3 said second lumen, fluid or an instrument may be
4 passed through said second lumen.
- 1 15. The device as recited in claim 14, wherein said
2 catheter defines a third lumen extending
3 longitudinally through said catheter from a third
4 port near said proximal end of said catheter to a

5 third opening near said distal tip of said
6 catheter.

1 16. The device as recited in claim 15, further
2 comprising:

3 a guide wire disposed through said third
4 lumen.

1 17. The device as recited in claim 14, wherein said
2 catheter defines a third lumen extending
3 longitudinally through said catheter for passing
4 fluid or an instrument therethrough.

1 18. A method for surgically cutting tissue of a patient
2 by using a catheter having at least a first lumen
3 and a second lumen defined therethrough, said first
4 lumen terminating in a first opening near a distal
5 end of said catheter and having a first
6 cutting/coagulating element disposed therethrough,
7 said second lumen terminating in a second opening
8 near said distal end of said catheter and having a
9 second cutting/coagulating element disposed
10 therethrough, comprising the steps of:

11 a. introducing said catheter, said first
12 cutting/coagulating element, and said second
13 cutting/coagulating element into said patient;
14 b. retracting said first cutting/coagulating
15 element until a portion of said first
16 cutting/coagulating element forms a bow
17 between a first location on said catheter near
18 said distal end of said catheter and a second
19 location on said catheter near said distal end
20 of said catheter;
21 c. manipulating said portion of said first
22 cutting/coagulating element and applying
23 energy thereto to incise tissue;

- 24 d. deploying said second cutting/coagulating
25 element relative to said distal end of said
26 catheter; and
27 e. manipulating said second cutting/coagulating
28 element and applying energy thereto to incise
29 tissue.

1 19. The method as disclosed in claim 18, further
2 comprising the steps of:
3 advancing a guide wire through said endoscope
4 and into said patient.

1 20. The method as disclosed in claim 19, further
2 comprising the steps of:
3 threading a third lumen of said catheter along
4 said guide wire.

1 21. The method as disclosed in claim 18, further
2 comprising the step of:
3 infusing a contrast fluid through a third
4 lumen of said catheter while said first
5 cutting/coagulating element remains in said
6 first lumen and said second
7 cutting/coagulating element remains in said
8 second lumen.

1 22. The method as disclosed in claim 18, further
2 comprising the step of:
3 withdrawing said second cutting/coagulating
4 element through said second lumen and infusing
5 a contrast fluid through said second lumen
6 while said first cutting/coagulating element
7 remains in said first lumen.

1 23. A method for surgically incising tissue of a
2 patient using a catheter having at least three
3 lumens defined therethrough, each lumen terminating

4 at a separate opening near a distal end of said
5 catheter, said first lumen having a first
6 cutting/coagulating element disposed therethrough,
7 said second lumen having a second
8 cutting/coagulating element disposed therethrough,
9 said third lumen having a guide wire disposed
10 therethrough, said first cutting/coagulating
11 element having a proximal end connected to a first
12 element deployer at said proximal end of said
13 catheter for deploying and retracting said first
14 cutting/coagulating element, said second
15 cutting/coagulating element having a proximal end
16 connected to a second element deployer at said
17 proximal end of said catheter for deploying and
18 retracting said second cutting/coagulating element,
19 comprising the steps of:
20 a. introducing said guide wire through an
21 endoscope and into said patient;
22 b. threading said catheter along said guide wire,
23 through said endoscope, and into said patient;
24 c. manipulating said first cutting/coagulating
25 element;
26 d. applying energy to said first
27 cutting/coagulating element to incise said
28 tissue;
29 e. deploying said second cutting/coagulating
30 element; and
31 f. applying energy to said second
32 cutting/coagulating to incise said tissue.

1 24. The method as disclosed in claim 23, further
2 comprising the step of:
3 infusing a contrast fluid through a fourth
4 lumen of said catheter while said first
5 cutting/coagulating element remains in said
6 first lumen, said second cutting/coagulating

7 element remains in said second lumen, and said
8 guide wire remains in said third lumen.

1 25. The method as disclosed in claim 23, further
2 comprising the step of:
3 withdrawing said second cutting/coagulating
4 element through said second lumen and infusing
5 a contrast fluid through said second lumen
6 while said first cutting/coagulating element
7 remains in said first lumen and said guide
8 wire remains in said third lumen.

1 26. The method as disclosed in claim 23, further
2 comprising the step of:
3 withdrawing said guide wire through said third
4 lumen and infusing a contrast fluid through
5 said third lumen while said first
6 cutting/coagulating cutting wire remains in
7 said first lumen and said second
8 cutting/coagulating element remains in said
9 second lumen.

1 27. A device for facilitating access to a duct within
2 the human body, comprising:
3 a. a catheter having a proximal end and a distal
4 tip and defining a first lumen and a second
5 lumen therethrough, wherein said first lumen
6 extends longitudinally through said catheter
7 from a first port near said proximal end of
8 said catheter to a first opening near said
9 distal tip of said catheter, and said second
10 lumen extends longitudinally through said
11 catheter from a second port near said proximal
12 end of said catheter to a second opening near
13 said distal tip of said catheter;
14 b. a first cutting wire disposed through said
15 first lumen and having a proximal end attached

16 to a first cutting wire deployer, said first
17 cutting wire deployer being attached to said
18 first port of said catheter;
19 c. a second cutting wire disposed through said
20 second lumen and having a proximal end and a
21 distal tip, said proximal end of said second
22 cutting wire being fixedly attached to a
23 second cutting wire deployer and said second
24 cutting wire deployer being attached to said
25 second port of said catheter, wherein said
26 distal tip of said second cutting wire extends
27 longitudinally through said second opening and
28 extends beyond said distal tip of said
29 catheter when said second cutting wire
30 deployer is in a fully-deployed position.

1 28. The device as recited in claim 27, wherein said
2 catheter defines a third lumen extending
3 longitudinally through said catheter from a third
4 port near said proximal end of said catheter to a
5 third opening near said distal tip of said
6 catheter, further comprising:
7 a guide wire disposed through said third
8 lumen.

1 29. The device as recited in claim 28, wherein said
2 catheter defines a fourth lumen extending
3 longitudinally therethrough.

1 30. A method for electrosurgically facilitating access
2 to the biliary tree of a patient using a catheter
3 having at least a first lumen and a second lumen
4 defined therethrough, said first lumen terminating
5 in a first opening near a distal tip of said
6 catheter and having a sphincterotome cutting wire
7 disposed therethrough, said second lumen
8 terminating in a second opening near said distal

9 tip of said catheter and having a needle knife
10 cutting wire disposed therethrough, said
11 sphincterotome cutting wire having a proximal end
12 connected to a sphincterotome deployer at said
13 proximal end of said catheter, said sphincterotome
14 cutting wire being in electrical communication with
15 a cutter, said sphincterotome deployer for
16 deploying and retracting said sphincterotome
17 cutting wire between a fully-deployed position and
18 a fully-retracted position relative to said distal
19 tip of said catheter, said sphincterotome cutting
20 wire being in electrical communication with a power
21 source, said needle knife cutting wire having a
22 proximal end connected to a needle knife deployer
23 at said proximal end of said catheter, said needle
24 knife deployer for deploying and retracting said
25 needle knife cutting wire between a fully-deployed
26 position and a fully-retracted position relative to
27 said distal tip of said catheter, said needle knife
28 cutting wire being in electrical communication with
29 a power source, comprising the steps of:
30 a. introducing said catheter, said sphincterotome
31 cutting wire in a deployed position, and said
32 needle knife cutting wire in a retracted
33 position through an endoscope and into the
34 duodenum of a patient near the entrance to the
35 common bile duct;
36 b. retracting said sphincterotome cutting wire
37 until said cutter forms a bow between a first
38 location on said catheter near said distal tip
39 of said catheter and a second location on said
40 catheter near said distal tip of said
41 catheter;
42 c. manipulating said sphincterotome cutter and
43 applying electrical current thereto to incise
44 tissue near said entrance of said common bile
45 duct;

- 46 d. deploying said sphincterotome cutting wire;
- 47 e. deploying said needle knife cutting wire
- 48 relative to said distal tip of said catheter;
- 49 f. manipulating said needle knife cutting wire
- 50 and applying electrical current thereto to
- 51 incise tissue near said entrance of said
- 52 common bile duct; and
- 53 g. retracting said needle knife cutting wire.

1 31. The method as disclosed in claim 30, further
2 comprising the steps of:

3 advancing a guide wire through said endoscope
4 and into said duodenum of said patient near
5 said entrance to said common bile duct; and
6 threading a third lumen of said catheter along
7 said guide wire.

1 32. The method as disclosed in claim 30, further
2 comprising the step of:

3 infusing a contrast fluid through a third
4 lumen of said catheter to visualize said
5 common bile duct while said sphincterotome
6 cutting wire remains in said first lumen and
7 said needle knife cutting wire remains in said
8 second lumen.

1 33. The method as disclosed in claim 30, further
2 comprising the step of:

3 withdrawing said needle knife cutting wire
4 through said second lumen and infusing a
5 contrast fluid through said second lumen to
6 visualize said common bile duct while said
7 sphincterotome cutting wire remains in said
8 first lumen.

1 34. A method for electrosurgically facilitating access
2 to the biliary tree of a patient using a catheter

3 having at least three lumens defined therethrough,
4 each lumen terminating at a separate opening near a
5 distal tip of said catheter, said first lumen
6 having a sphincterotome cutting wire disposed
7 therethrough, said second lumen having a needle
8 knife cutting wire disposed therethrough, said
9 third lumen having a guide wire disposed
10 therethrough, said sphincterotome cutting wire
11 having a proximal end connected to a sphincterotome
12 deployer at said proximal end of said catheter,
13 said sphincterotome cutting wire being in
14 electrical communication with a cutter, said
15 sphincterotome deployer for deploying and
16 retracting said sphincterotome cutting wire between
17 a fully-deployed position and a fully-retracted
18 position relative to said distal tip of said
19 catheter, said sphincterotome cutting wire being in
20 electrical communication with a power source, said
21 needle knife cutting wire having a proximal end
22 connected to a needle knife deployer at said
23 proximal end of said catheter, said needle knife
24 deployer for deploying and retracting said needle
25 knife cutting wire between a fully-deployed
26 position and a fully-retracted position relative to
27 said distal tip of said catheter, said needle knife
28 cutting wire being in electrical communication with
29 a power source, comprising the steps of:
30 a. introducing said guide wire through an
31 endoscope and into the duodenum of a patient
32 near the entrance to the common bile duct;
33 b. threading said catheter along said guide wire,
34 through said endoscope, and into said duodenum
35 of said patient near said entrance to said
36 common bile duct;
37 c. deploying said needle knife cutting wire
38 relative to said distal tip of said catheter;

- 39 d. manipulating said needle knife cutting wire
40 and applying electrical current thereto to
41 incise tissue near said entrance of said
42 common bile duct;
43 e. retracting said needle knife cutting wire;
44 f. retracting said sphincterotome cutting wire
45 until said cutter forms a bow between a first
46 location on said catheter near said distal tip
47 of said catheter and a second location on said
48 catheter near said distal tip of said
49 catheter;
50 g. manipulating said sphincterotome cutter and
51 applying electrical current thereto to incise
52 tissue near said entrance of said common bile
53 duct; and
54 h. deploying said sphincterotome cutting wire.

1 35. The method as disclosed in claim 34, further
2 comprising the step of:
3 infusing a contrast fluid through a fourth
4 lumen of said catheter to visualize said
5 common bile duct while said sphincterotome
6 cutting wire remains in said first lumen, said
7 needle knife cutting wire remains in said
8 second lumen, and said guide wire remains in
9 said third lumen.

1 36. The method as disclosed in claim 34, further
2 comprising the step of:
3 withdrawing said needle knife cutting wire
4 through said second lumen and infusing a
5 contrast fluid through said second lumen to
6 visualize said common bile duct while said
7 sphincterotome cutting wire remains in said
8 first lumen and said guide wire remains in
9 said third lumen.

1 37. The method as disclosed in claim 34, further
2 comprising the step of:

3 withdrawing said guide wire through said third
4 lumen and infusing a contrast fluid through
5 said third lumen to visualize said common bile
6 duct while said sphincterotome cutting wire
7 remains in said first lumen and said needle
8 knife cutting wire remains in said second
9 lumen.

1 38. A device for electrosurgically facilitating access
2 to the biliary tree of the human body, comprising:

- 3 a. a catheter having a proximal end and a distal
4 end;
- 5 b. a first lumen of said catheter, said first
6 lumen extending longitudinally through said
7 catheter from a first port near said proximal
8 end of said catheter to a first opening near
9 said distal end of said catheter;
- 10 c. a second lumen of said catheter, said second
11 lumen extending longitudinally through said
12 catheter from a second port near said proximal
13 end of said catheter to a second opening at
14 said distal end of said catheter;
- 15 d. a third lumen of said catheter, said third
16 lumen extending longitudinally through said
17 catheter from a third port near said proximal
18 end of said catheter to a second opening at
19 said distal end of said catheter;
- 20 e. a sphincterotome cutting wire disposed through
21 said first lumen and having a proximal end and
22 a distal tip, and wherein a portion of said
23 sphincterotome cutting wire exits said first
24 lumen through a cutting wire port and reenters
25 said catheter through an anchor port, thereby
26 forming a cutter outside of said catheter;

- 27 f. a sphincterotome deployer attached to said
- 28 proximal end of said sphincterotome cutting
- 29 wire;
- 30 g. a needle knife cutting wire disposed through
- 31 said second lumen and having a proximal end
- 32 and a distal tip, said distal tip protruding
- 33 beyond said distal end of said catheter in an
- 34 axial direction when said needle knife cutting
- 35 wire is in a fully-deployed position;
- 36 h. a needle knife deployer attached to said
- 37 proximal end of said needle knife cutting
- 38 wire; and
- 39 i. a guide wire disposed through said third
- 40 lumen.

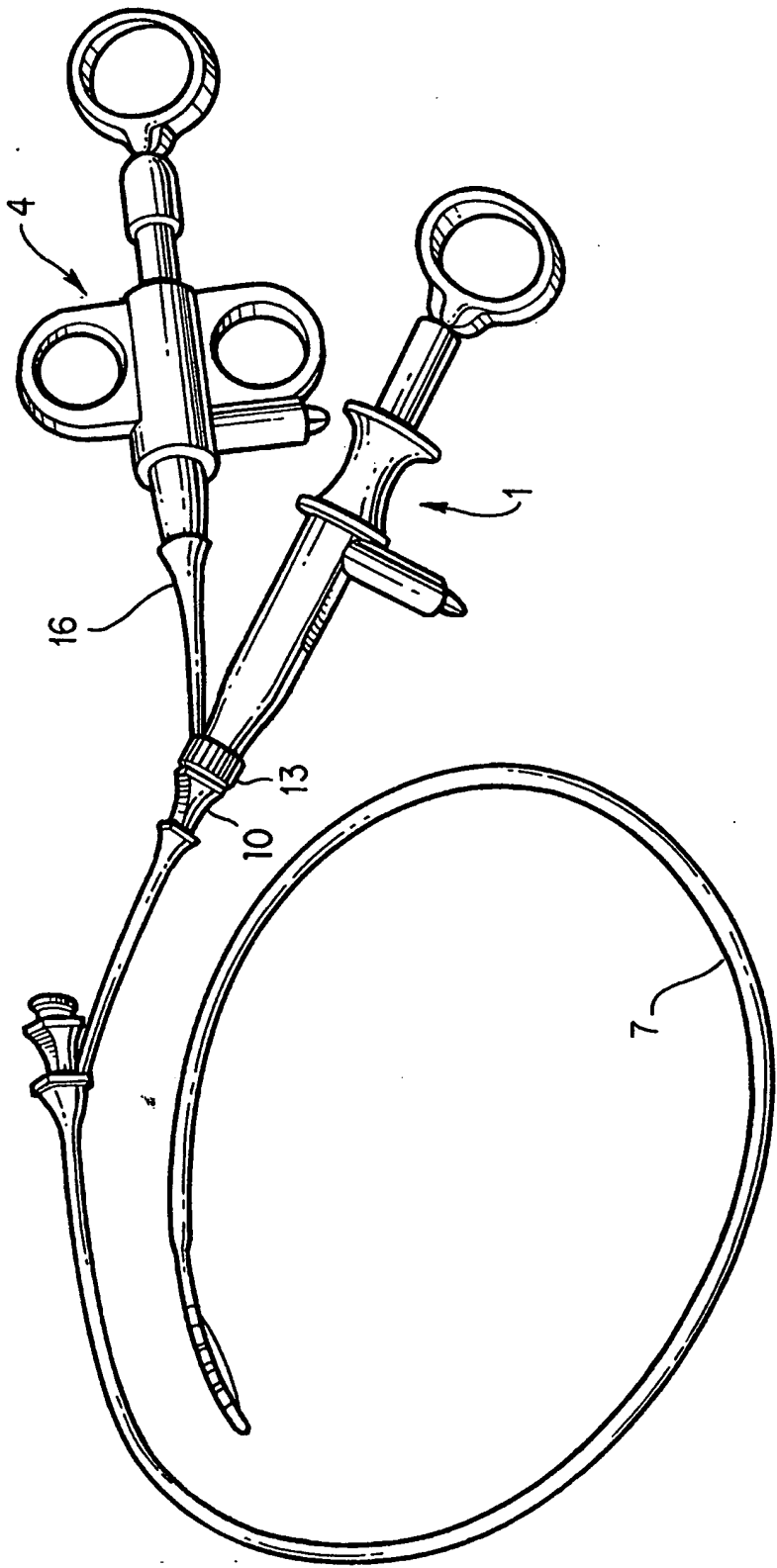


FIG.1

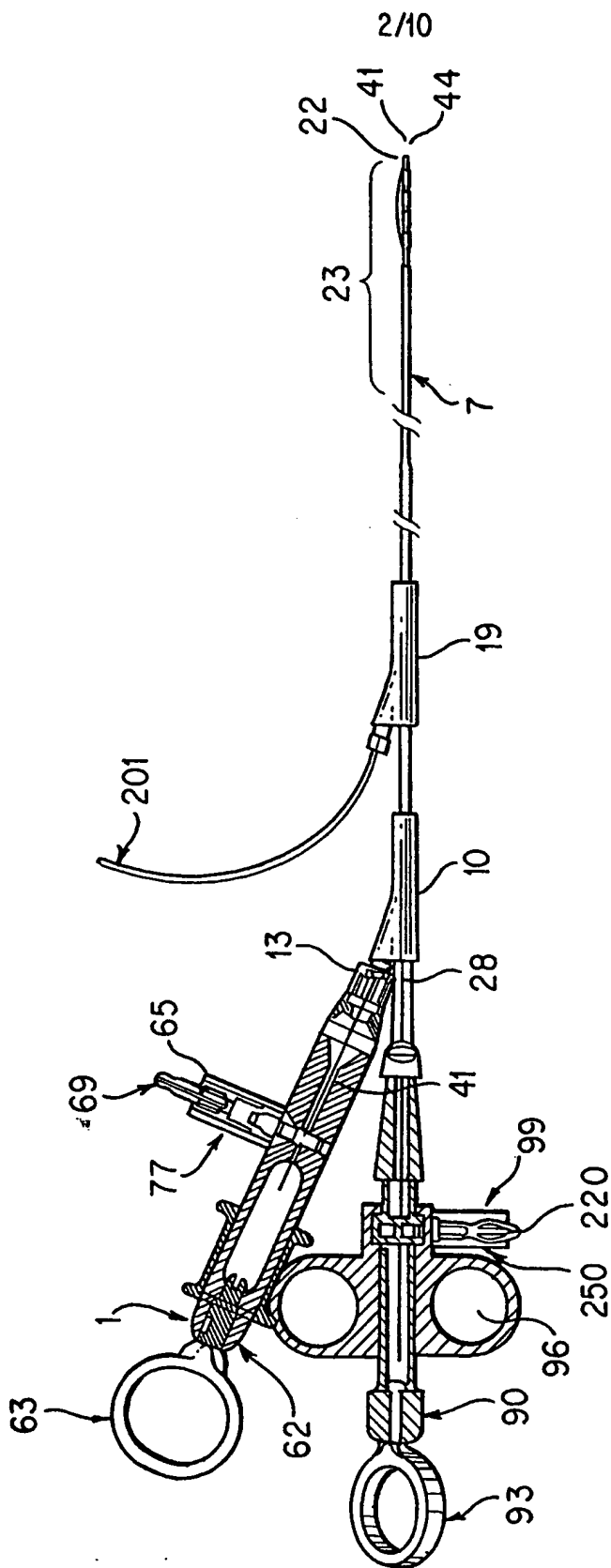


FIG. 2

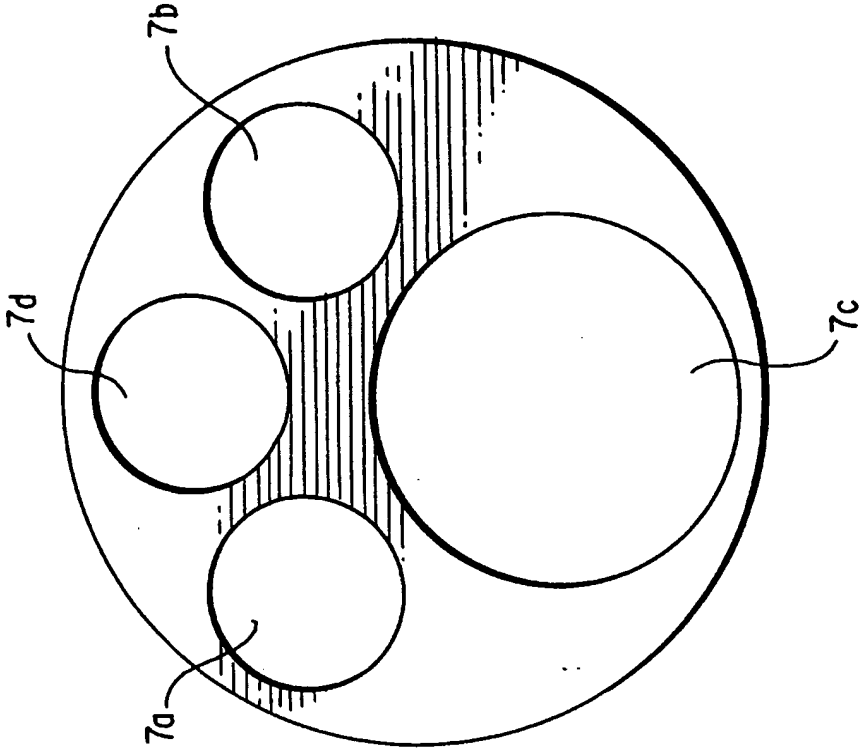


FIG. 2B

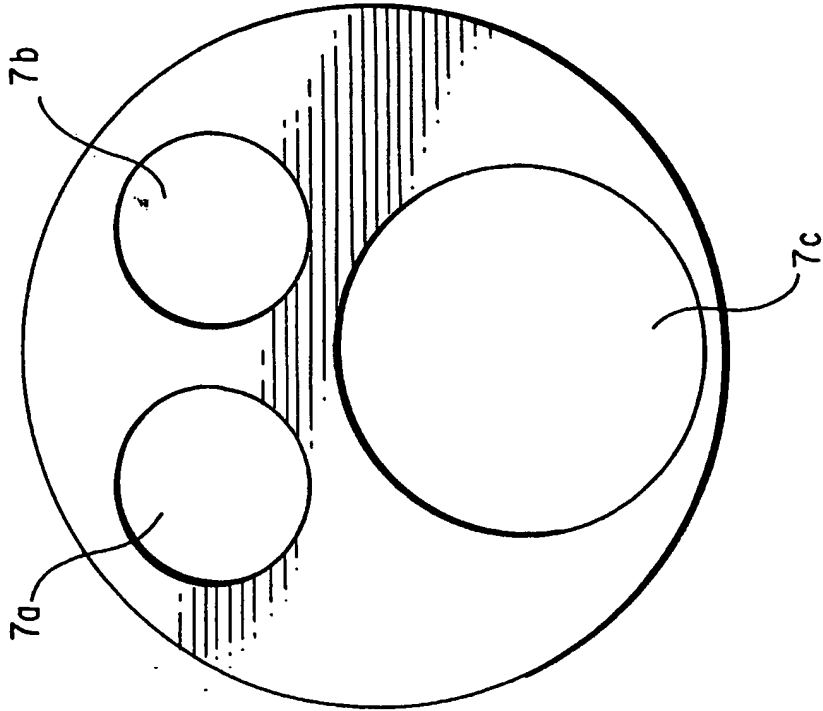


FIG. 2A

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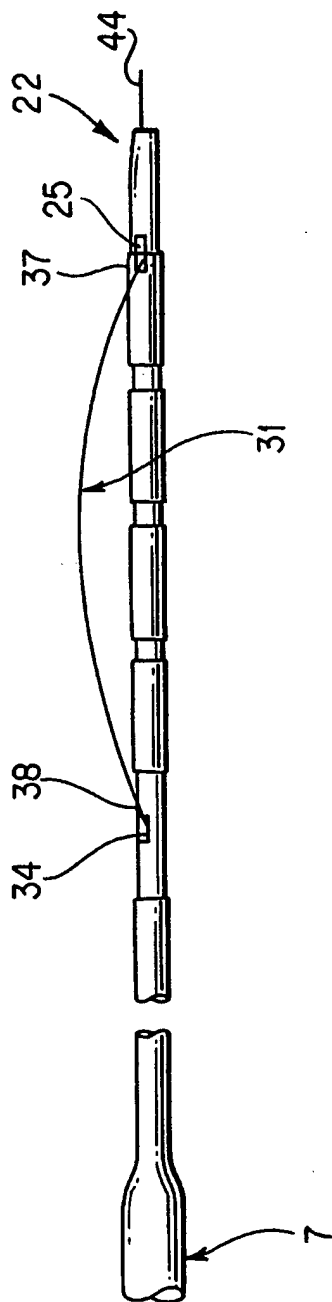


FIG. 3

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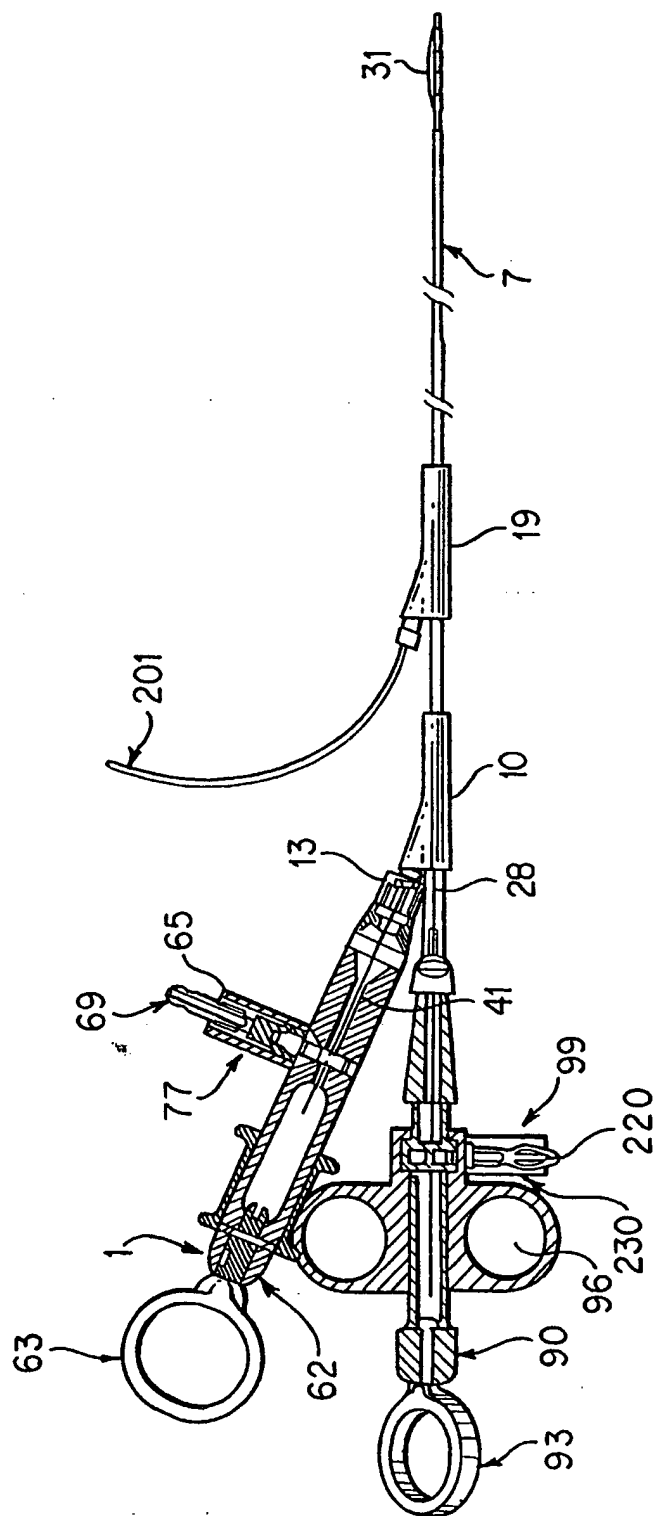


FIG. 4

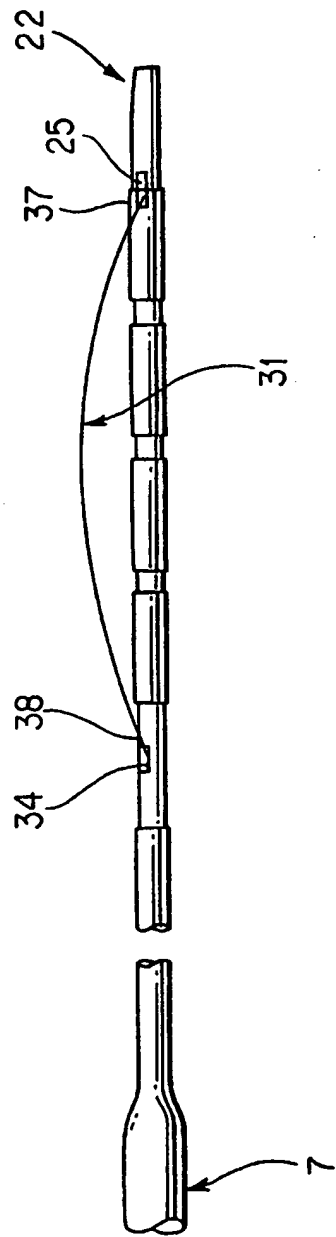


FIG. 5

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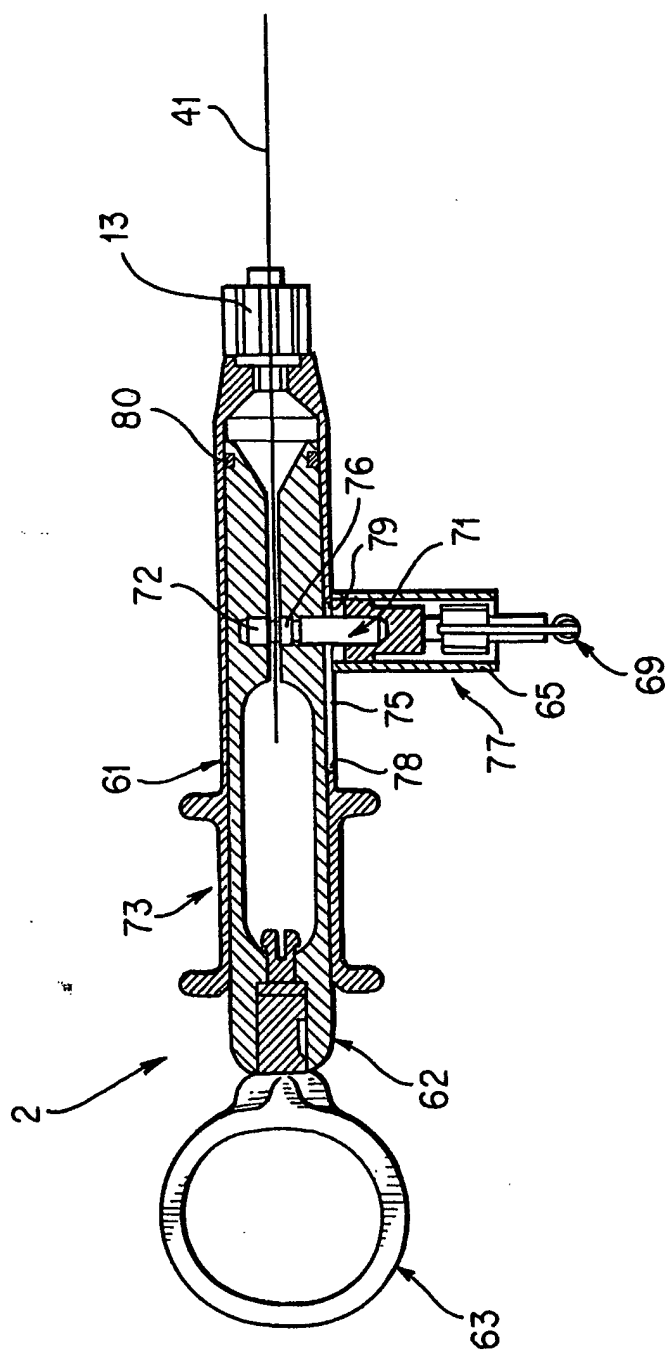


FIG. 6

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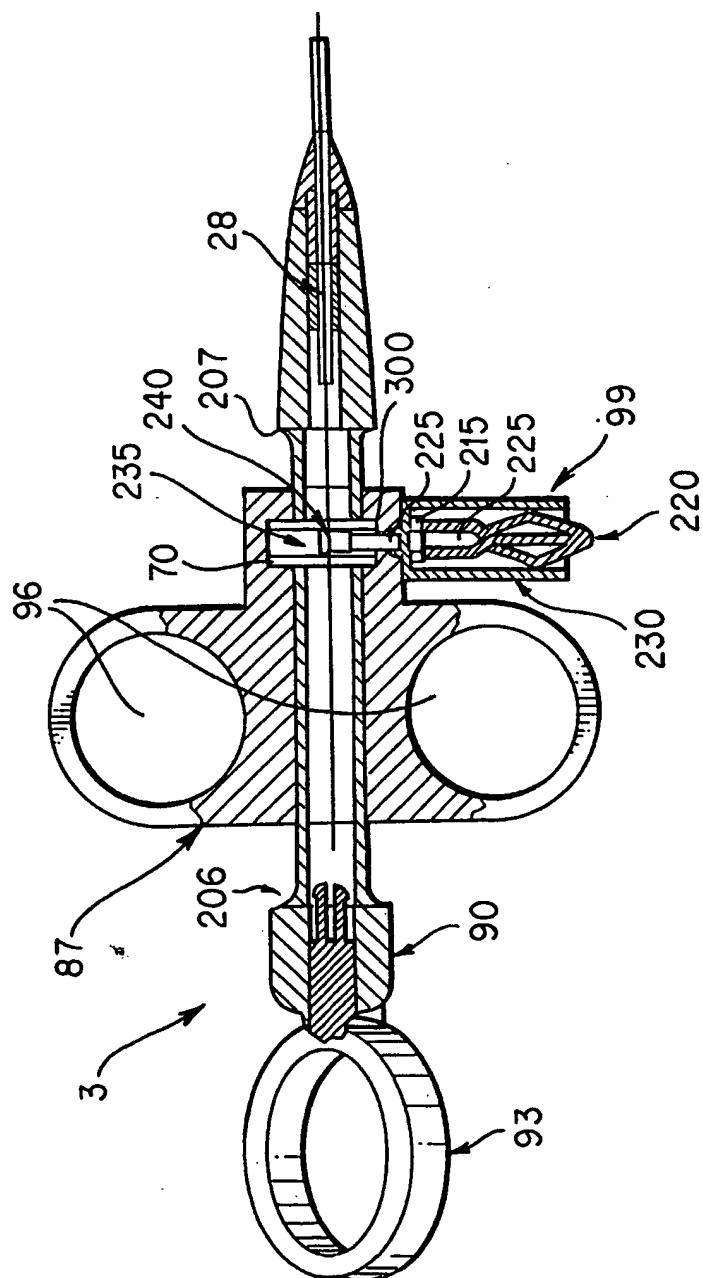


FIG. 7

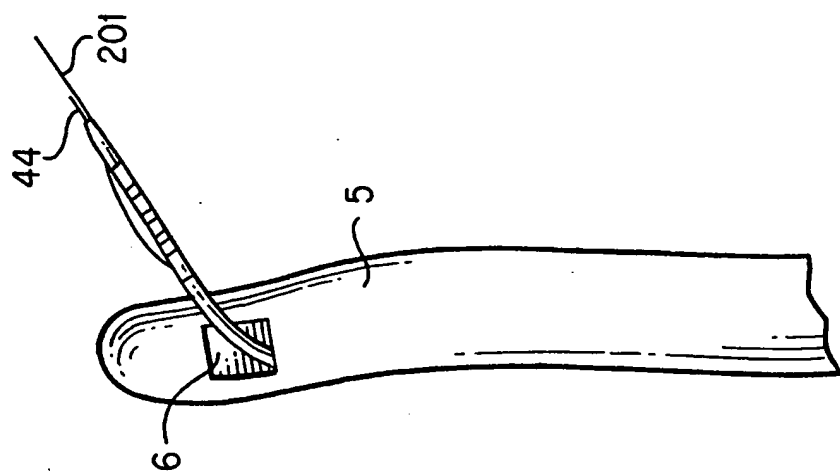


FIG. 9

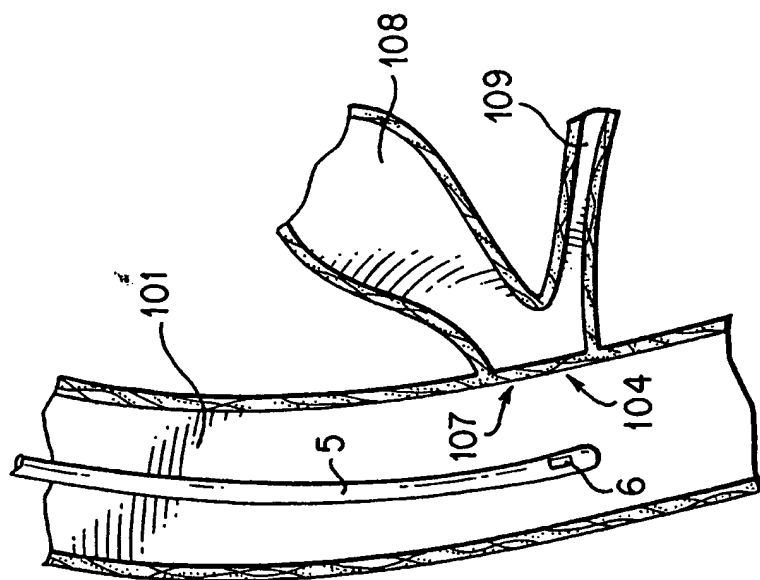


FIG. 8

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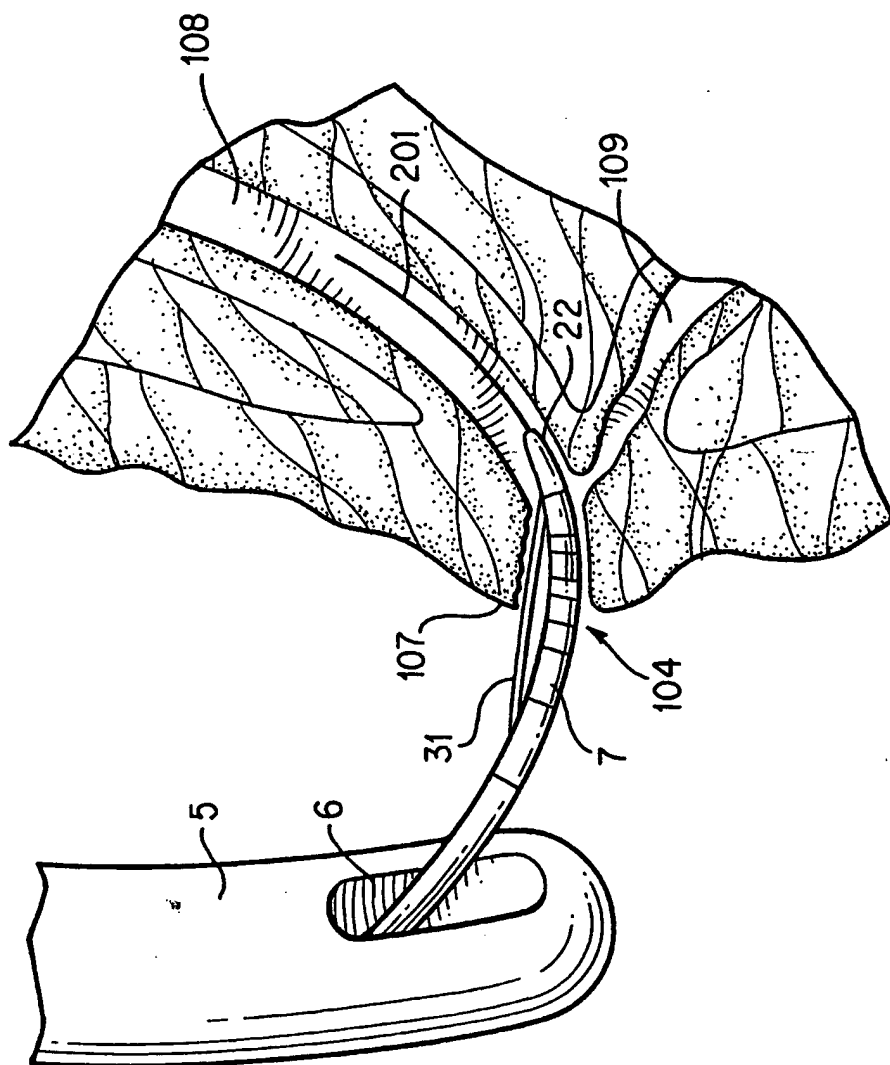


FIG. 10

INTERNATIONAL SEARCH REPORT

Int ional Application No

PCT/US 98/20827

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/38

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	DE 87 11 635 U (GIP GASTROINTESTINALE PRODUKTE VERTRIEBS GMBH) 21 January 1988 see page 5; figure 2	1,2,9, 14,27 3-8, 10-13, 15-17, 28,29,38
Y	US 5 643 199 A (ROWLAND CHRISTOPHER A ET AL) 1 July 1997 see column 4, line 52 - column 5, line 13 see column 5, line 34 - line 40; figures 1,2,6 --- -/--	3-8, 10-13, 15-17, 28,29,38

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

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Date of the actual completion of the international search

1 February 1999

Date of mailing of the international search report

15/02/1999

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/20827

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 342 295 A (IMRAN MIR A) 30 August 1994 see column 2, line 29 - line 47 see column 3, line 17 - line 31 ----	6,8,13, 29
A	US 4 485 812 A (HARADA SHINICHI ET AL) 4 December 1984 see figure A ----	1
P,X	US 5 788 681 A (JACOB HAROLD ET AL) 4 August 1998 see column 12, line 50 - column 13, line 39 -----	38

INTERNATIONAL SEARCH REPORT

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 18-26, 30-37
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT- Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Int. Application No

PCT/US 98/20827

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